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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/728,711	11/30/2000	Y. Tom Tang	21272-048CIP2C	4871

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EXAMINER	
EINSMANN, JULIET CAROLINE	
ART UNIT	PAPER NUMBER
1634	8

DATE MAILED: 05/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/728,711	Applicant(s) TANG ET AL.	
	Examiner Juliet Einsmann	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 January 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-28* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 2, 3, 4, 5, 6, 7, 8, 9, 22, 23, 24, 25, and 26, drawn to nucleic acids, vectors, host cells, and arrays, classified in class 536, subclass 23.1.

II. Claims 10, 11, 20, and 21, drawn to polypeptides, classified in class 530, subclass 300.

III. Claim 12, drawn to antibodies, classified in class 530, subclass 387.1.

IV. Claims 13-15, drawn to methods for detecting nucleic acids, classified in class 435, subclass 6.

V. Claim 16, drawn to method of detecting polypeptides, classified in class 435, subclass 7.1.

VI. Claims 17-18, drawn to methods of identifying compounds that bind polypeptides, classified in class 436, subclass 501.

VII. Claim 19, drawn to methods of producing polypeptides, classified in class 435, subclass 69.1.

VIII. Claim 27, drawn to method of treatment using polypeptides, classified in class 424, subclass 184.1.

IX. Claim 28, drawn to methods of treatment using antibodies, classified in class 424, subclass 130.1.

Further Restriction Requirement Applicable to All Groups

Each group detailed above reads on 10 patentably distinct groups, wherein each of the distinct groups is drawn to a product associated with a separate polynucleotide sequence identified by SEQ ID NO. Applicants must further single sequence for examination with whichever claim set is elected.

Applicant is advised that examination will be restricted to only the elected SEQ ID NO. and should not to be construed as a species election. Prior to allowance, non-elected subject matter will be required to be deleted from any allowable claims.

The inventions are distinct, each from the other because of the following reasons:

2. The inventions of Groups I, II, and III are patentably distinct because they are drawn to different products having different structures and functions. The nucleic acid of Group I is composed of nucleotides linked in phospodiester bonds and arranged in space as a double helix. The polypeptide of Group II is composed of amino acids linked in peptide bonds and arranged spatially in a number of different tertiary structures including alpha helices, beta-pleated sheets, and hydrophobic loops (transmembrane domain). Although the polynucleotides and polypeptides are related as the claimed polynucleotide is asserted to encode the claimed polypeptide, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein as evidenced by the methods of at least group IV. The antibody of Group III is also composed of amino acids linked

in peptide bonds and arranged spatially in a very specific tertiary structure that allows that antibody to specifically bind to particular regions, i.e. epitopes, of the encoded polypeptide. Further, antibodies are glycosylated and their tertiary structure is unique, where four subunits (2 light chains and 2 heavy chains) associated via disulfide bonds into a Y-shaped symmetric dimer. Furthermore, the products of Groups I, II, and III can be used in materially different processes, for example, the DNA of Group I can be used in hybridization assays, the antibody of Group III can be used in immunoassay, the polypeptide of Group II can be used to make fusion protein with an enzymatic function. Consequently, the reagents, reaction conditions, and reaction parameters required to make or use each invention are different. Therefore, the inventions of Groups I, II, and III are patentably distinct from each other.

3. Inventions I and IV and inventions I and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids of invention I can be used in a variety of methods, such as hybridization assays, for protein expression, nucleic acid purification assays, expression assays, and aptamer assays.

4. Invention I is unrelated to inventions V, VI, VIII, and IX. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the cited methods do not require or recite the use of the nucleic acids of invention I.

5. Invention II is unrelated to inventions IV and IX. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the cited methods do not require or recite the use of the polypeptides of invention II.

6. Inventions II is related to inventions V, VI, and VII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products of invention II can be used in materially different methods, as is evidenced by the methods disclosed herein.

7. Inventions II and VII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the polypeptides of invention II can be obtained by other processes such as via chemical synthesis or isolation from nature.

8. Invention III is unrelated to inventions IV, V, VI, VII, and VIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the cited methods do not require or recite the use of the antibodies of invention III.

9. Inventions III and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case antibodies of invention III can be used in other methods such as in an immunoassay or to purify the protein to which it binds.

10. The methods of inventions IV, V, VI, VII, VIII, and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are each methods that have different goals from the other, require distinct method steps from the others, and utilize separate reagents from the others.

11. With regard to the restriction between individual sequences, each sequence is patentably distinct because they are unrelated sequences, i.e. these sequences are unrelated because they do not share a common structure. A reference against one would not anticipate or obviate another, and thus for each particular sequence a separate search of the patent and non-patent literature is required. These separate searches would impose undue burden on the examiner.

12. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as demonstrated by their different classification and recognized divergent subject matter and because inventions I-IX require different searches that are not coextensive, examination of these claims would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

13. A telephone call was made to Ivor Elrifi on 5/6/02 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

14. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C. Einsmann whose telephone number is (703) 306-5824. The examiner can normally be reached on Monday through Friday, from 9:00 AM until 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Juliet C. Einsmann
Examiner
Art Unit 1634

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600

May 6, 2002